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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,009	12/02/2003	Andrew Geall	1530.0620001/EKS/UWJ	3175

26111 7590 09/12/2007
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/725,009	Applicant(s) GEALL, ANDREW	
	Examiner Ja-Na Hines	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 August 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *1-45*.
   Claim(s) withdrawn from consideration: *None*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

The proposed after final amendment will not be entered because the amendment raises new issues that require further search and consideration. The new issues are drawn to the method of preparation now requiring the step of cold filtering the mixture; however the previous claims did not require the cold filtration step. Therefore the amendment will not be entered.

The new matter rejection over claims 1-45 under 35 U.S.C. 112, first paragraph, is maintained because applicant did not point to support in the specification for a method of preparing a lyophilized composition or a composition comprising a compound selected from the group consisting of mixtures thereof.

The rejection of claims 1-2, 5, 8-13, 15-24, 27-32, 37-39 and 40-45 under 35 U.S.C. 102(b) as being anticipated by Evans (WO 02/00844) in view of Volkin et al., (WO 97/408839). The rejection is maintained because it would have been prima facie obvious at the time of applicants' invention to apply lyophilized polynucleotide formulations at a temperature below the cloud point of said block copolymer to form a mixture; and (b) lyophilizing the mixture in order to optimize the stability of the polynucleotide and provide stable long term polynucleotide formulations since one of ordinary skill in the art would have a reasonable expectation of success by modifying the method of preparation because both Evans and Volkin et al., teach the desirability of providing stable polynucleotide vaccines achieved by the specific formulations of Evans and Volkin et al., since Volkin et al., teach that disaccharide sugars such as sucrose and lactose greatly increase stabilization of lyophilized polynucleotide formulations.

The rejection of claim 3 under 35 U.S.C. 103(a) as being unpatentable over Evans (WO 02/00844) and Volkin et al., (WO 97/408839) further in view of Balasubramaniam (US Patent 5,824,322) is maintained. The grounds of rejection were on the basis that it would have been prima facie obvious at the time of applicants' invention to apply compositions containing biologically-active copolymer as taught by Balasubramaniam to Evans and Volkin et al's method of preparing a lyophilized composition because one of ordinary skill in the art would have a reasonable expectation of success by modifying the method of preparation because Evans, Volkin et al., and Balasubramaniam teach the desirability of providing preparations containing physiologic phosphate buffered saline and freeze-dried (lyophilized) formulations.

The rejection of claims 4, 6-7 and 25-26 under 35 U.S.C. 103(a) as being unpatentable over Evans (WO 02/00844) and Volkin et al., (WO 97/408839) in view of Hunter et al., (US Patent 5,811,088) is maintained because it would have been prima facie obvious at the time of applicants' invention to apply lyophilized polynucleotide formulations cmprising the step as taught by Hunter et al., to method of preparing a lyophilized composition as taught by Evans and Volkin et al., in order to provide sterile block copolymer formulations because one of ordinary skill in the art would have a reasonable expectation of success by modifying the method of preparation because both Evans and Volkin et al., teach the desirability of providing formulations containing block copolymers at a temperature at which they are soluble, i.e., below their cloud point, and Hunter et al., teach that the same soluble block copolymers.

The rejection of claims 11-14 under 35 U.S.C. 103(a) as being unpatentable over Evans (WO 02/00844) and Volkin et al., (WO 97/408839) in view of Munsunuri et al., (WO 99/21591) is maintained. The rejection is on the grounds that it would have been prima facie obvious at the time of applicants' invention to include concentrations of sucrose as taught by Munsunuri et al., in the method of preparing a lyophilized composition as taught by Evans and Volkin et al., in order to optimize the stability of the polynucleotide and provide stable long term polynucleotide formulations in order to adjust and achieve desirable tonicity in the compositions. One of ordinary skill in the art would have a reasonable expectation of success by modifying the method of preparation because Evans, Volkin et al., and Munsunuri et al., already teach sugars such as sucrose will greatly stabilize lyophilized polynucleotide formulations.

The rejection of claims 33-36 under 35 U.S.C. 103(a) as being unpatentable over Evans (WO 02/00844) and Volkin et al., (WO 97/408839) in view of Felgner et al., (US Patent 5,459,127) is maintained for reasons of record. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants' invention to include the cationic surfactants of claims 33-36 as taught by Felgner et al., in the method of preparing a lyophilized composition as taught by Evans and Volkin et al., in order to effectively deliver polynucleotides formulations intracellularly because no more than routine skill would have been required to incorporate the cationic surfactants of claims 33-36 as taught by Felgner et al., into the methods and compositions of Evans and Volkin et al., because Felgner et al., teach that surfactants as enhancing the effectiveness of the lipids in interacting with the cell membrane.

MARK NAVARRO
PRIMARY EXAMINER